



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Garvey**

Application No: **10/760,672**

Group Art Unit: **1654**

Filed: **January 21, 2005**

Examiner: **Maury A. Audet**

For: **Methods of Use for Novel Sulfur Containing Organic Nitrate Compounds**

Attorney Docket No: **102258.137 US2**

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**Provisional Response to Restriction Requirement and
Request for Reconsideration of Restriction Requirement Under 37 C.F.R. § 1.143**

This response is submitted in reply to the Restriction Requirement dated January 13, 2005, for which a response is due on or before February 14, 2005 (the first business day following Sunday, February 13, 2005).

No fee is believed to be due; however, the Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219 to maintain the pendency of the present application.

I. Request for Reconsideration of Restriction Requirement

Under 37 C.F.R. §1.143, Applicants respectfully request reconsideration of the restriction requirement dated May 27, 2004.

The Examiner restricted the invention 75-ways as follows:

Groups 1-38	Claims 1-4	Methods of use for the compounds of Formula (I)
Groups 39-75	Claims 1-3 and 5	Methods of use for the compounds of Formula (II)

The claims in the pending application are directed to methods of use for the compounds of Formula (I) and (II).

II. Restriction is Not Proper When the Claims are Related

As stated in MPEP §808.02, “[w]here, as disclosed in the application, the several inventions claimed are related, and such related inventions are not patentably distinct as claimed, restriction under 35 U. S. C. §121 is never proper (MPEP §806.05).”

Some of the pending claims are related. Thus, the restriction requirement is not proper. To show that the inventions are distinct, the Examiner must show either that (1) there is a separate classification of the claims; (2) a separate status in the art when they are classifiable together; or (3) a different field of search. *In re Kase*, USPQ2d 1063 (US PTO Director, 2004).

None of these three criteria have been shown with some of the claims of this application:

A search of the prior art for the methods for treating and/or preventing gastrointestinal disorders with the compounds of the invention (i.e. Groups 7 and 45) would necessarily encompass a search of the prior art for their methods of use for treating other gastrointestinal disorders such as treating and/or improving the gastrointestinal properties of COX-2 inhibitors; for decreasing the recurrence of ulcers; for treating and/or improving the gastrointestinal properties of COX-2 inhibitors; for improving gastroprotective properties, anti-*Helicobacter pylori* properties or antacid properties of proton pump inhibitors; and for improving gastroprotective properties of H₂ receptor antagonists.

Thus, the prior art for the treating and/or preventing gastrointestinal disorders with the compounds of the invention, will also be the same prior art for their methods of use for treating other gastrointestinal disorders such as treating and/or improving the gastrointestinal properties of COX-2 inhibitors; for decreasing the recurrence of ulcers; for treating and/or improving the gastrointestinal properties of COX-2 inhibitors; for improving gastroprotective properties, anti-*Helicobacter pylori* properties or antacid properties of proton pump inhibitors; for improving gastroprotective properties of H₂ receptor antagonists (i.e., Groups 11, 14, 15 and 20 or Groups 48, 51, 52 and 57). Also, some of the gastrointestinal disorders of the Examiner’s Groups 7, 11, 14, 15 and 20 or Groups 45, 48, 51, 52 and 57 are encompassed within the definition of gastrointestinal disorders in the specification, at, for example page 10, lines 2-10.

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If the methods for treating and/or preventing gastrointestinal disorders with the compounds of the invention are allowable (Examiner's Groups 7 or 45), then all the other gastrointestinal disorders methods of use for these compounds would also be allowable (Examiner's Groups 11, 14, 15 and 20 or Groups 48, 51, 52 and 57). *In re Kase*, USPQ2d 1063 (US PTO Director, 2004).

III. Proposed restriction requirement

Applicants respectfully propose the all the methods of use for treatment of gastrointestinal disorders by the compounds of Formula (I) or Formula (II) be examined together. Applicants respectfully propose that the following groups be examined together:

Group A	Examiner's Groups 7, 11, 14, 15 and 20
Group B	Examiner's Groups 45, 48, 51, 52 and 57.

IV. Provisional Response to Restriction Requirement

Applicants provisionally elect Group 45, claims 1-3 and 5 drawn to the methods for treating and/or preventing gastrointestinal disorders by the compounds of Formula II, with traverse.

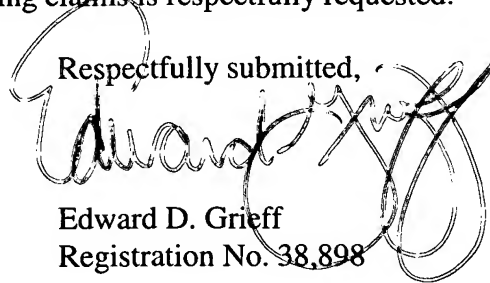
V. Election of Species

In response to the election of species requirement, Applicants elect N-(3-nitratopivaloyl)S-pivaloyl-cysteine ethyl ester (i.e., SPM 4757) as the compound of Formula (II); and elect "peptic ulcers" as the gastrointestinal disorder (specification at page 10, line 4).

VI. Conclusion

Applicants respectfully request that the restriction requirement be withdrawn and be replaced with Applicant's proposed restriction requirement. An early and favorable consideration and allowance of the pending claims is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Edward D. Grieff", is written over the typed name and registration number.

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Date: February 14, 2005
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